# Exhibit 1

#### Diagnostics review of Theranos' Technology and Final Recommendations Shane Weber 12/31/08

#### Overview:

Theranos Systems (Theranos) purports to have a patient home use immunoassay in vitro diagnostic device platform. They have repeatedly introduced this platform to multiple individuals (a partial list below) at Pfizer over the last few years. The purpose of this review was to close the loop on all previous efforts for Theranos to look for business opportunities with Pfizer, and to make final recommendations regarding potential future attempts for Theranos to engage different parts of Pfizer in their platform. Theranos describes their platform as used by the patient to measure self finger pricked blood samples. The assay result is available to the patient or is provided wirelessly back to a physician. The Theranos platform is not an approved FDA diagnostic nor is a CLIA Laboratory Developed Test.

#### Recommendations:

- 1) Theranos does not at this time have any diagnostic or clinical interest to Pfizer.
- 2) It is recommended that no further financial investment or clinical sample resources be extended to Theranos.
- 3) Going forward Theranos should be monitored by Molecular Medicine's Diagnostic group. Given Theranos' engagement of MM Oncology TAMMLs, the Diagnostics group will keep the TAMML group apprised of any relevant improvements in Theranos' technologies. A once every six month phone call (or as may be requested by Theranos upon a significant improvement to their platform) via specified point of contacts on both sides is sufficient to monitor and determine if Theranos has any demonstrated capability. Theranos has been excessively pushy in accessing new points of contact once turned down by an existing point of contact. Their multiple interactions cause undue distraction from our ongoing work and cause us business inefficiency. A regular monitoring will manage them so they have no basis to claim they must contact others because they are not being paid attention. Additionally if Theranos does contact others then Molecular Medicine will have an ongoing status and position report to counsel those contacted.

#### Review and Comments on Thernos Provided Information:

The technical assessment review process consisted of examining Theranos confidential summary reports, reading their public patent publications, hearing their story in a one hour teleconference with questions and answers, reading their answers to a written set of technical due diligence questions submitted to them, surveying the web for public information of interest and discussing with two oncology Therapeutic Area Molecular Medicine Leads their interest for potential utility in current or for seen clinical trials.

During this process Theranos provided summary reports on studies with GlaxoSmithKline and Novartis. To date they have not responded to requests confirming that these are non-confidential reports that can be shared and so these reports have been

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returned to them.

The Introduction to Theranos Systems slide deck does not contain sufficient information on their platform to demonstrate in vitro diagnostic assay or platform capability.

Theranos has provided a poorly prepared summary document of their platform for home patient use with anti-angiogenic therapics. A small number patients receiving Sutent and other anti-EGFR receptor or anti-angiogenesis therapies were measured with the Theranos System platform.

- 1. Theanos Systems in the slide deck states "Huge variation between subjects, both absolute levels and changes over time vary greatly". No discussion or rigorous graphical multi-parameter quantitative analysis of the patient cohort was done to elucidate and provide clarity of correlation to clinical response.
- 2. Theranos unconvincingly argues the case for having accomplished tasks of interest to Pfizer.
- 3. The nine conclusions in their summary document are not believable based on the information provided.

Theranos has provided non-informative, tangential, deflective or evasive answers to a written set of technical due diligence questions. The questions and answers are in the background and supporting information at the end of this document.

## Therapeutic Area Molecular Medicine Lead (TAMML) Interest in Theranos or a Theranos-like Home Patient Immunoassay In Vitro Diagnostic Platform:

- 1. Verbal half hour consultations with Oncology TAMMLs Andy Williams, La Jolla and Michael Robbins, NYC, determined that they have no current interest or in the for seeable future for a patient home in vitro immunoassay diagnostic in any current or planned oncology clinical Phase I, II or III study.
- Neither TAMML was interested in a proof of concept study for supporting another company's research and development program that does not serve their program needs.

### Diagnostic Group, Molecular Medicine Interest in Theranos or a Theranos-like Home Patient Immunoassay In Vitro Diagnostic Platform:

- 1. The diagnostic oncology assay needs currently for us are molecular nucleic acid tests run in physician care sites as point of care decisions for patient enrollment into clinical studies or later upon drug approval as a companion diagnostic. The interest is not for immunoassays run by patients in their homes. The Theranos platform does not do molecular nucleic acid tests, would require years of time and investment in order to do so and existing alternatives exist today from other companies.
- 2. The diagnostic group has identified companies with working nucleic in vitro diagnostic assay platforms to support the molecular test needs of the Pan Her and CDX-110 studies as well as future Maraviroc tropism tests.
- 3. Another diagnostic immunoassay assay of interest is very highly sensitive sepsis assays run at the point of care physician site not at home by the patient. Sepsis assays will require sample concentration. The Theranos platform does not

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provide integrated sample concentration from milliliters into microliter test volumes, nor does it have a chemiluminescent sensitive detection capability.

#### Due Diligence Questions Verbally Asked to Theranos in Nov. 13th Teleconference:

Theranos verbally provided oblique, deflective or evasive non-informative answers to these technical due diligence questions below.

- 1. For what medical need does Theranos think the device platform will first be clinically used?
- 2. What medical needs does Theranos currently have the device platform in use?
- 3. What is the Theranos plan and status of registering the device platform with the FDA? Does Theranos have a 510(k) predicate identified or is this a denov 510(k) instrument filing?
- 4. How does Theranos view the device platform in relation to the draft FDA guidance on IVD-Multi Algorithm Index assays?
- 5. What is Theranos plan for reimbursement of diagnostic tests from their device platform? <a href="http://vcnturebeat.com/2006/12/07/theranos-raises-285m-for-device-tracking-effects-of-drugs-on-patients/">http://vcnturebeat.com/2006/12/07/theranos-raises-285m-for-device-tracking-effects-of-drugs-on-patients/</a>
- 6. What is the approximate anticipated cost of the device if one hundred were desired for a clinical study enrollment?

#### Theranos Funding:

- 1. Theranos, has raised \$28.5 million of a \$30 million planned third round according to a filing with the Securities and Exchange Commission.
- 2. The company raised more than \$10 million in a second round in March, and an undisclosed amount in 2004 first round.

#### **Intellectual Property of Interest:**

- 1. There is the one Theranos issued patent and 5 applications.
- 2. The claims describe a wearable microarray device for ELISAs, particularly for measuring insulin and/or glucose.
- 3. It is a fluorescent waveguide device, not chemiluminescent.
- 4. Chemiluminescent is the conventional preferred commercial choice for in vitro diagnostic platform detection.

#### Due Diligence Questions sent Nov. 17 to Theranos and their Nov. 27 Answers:

- 1. In the summary document you refer to meeting with the Pfizer team. Who was the Pfizer team? Angeliki Kostianti
- 2. To Pfizer point of contacts changing several times, who chronologically were the Pfizer point of contacts? Peter Corr and Nick Saccomano. Then David Lester. Then Angeliki Kostianti. Then Luis Parodi. Now Aidan Power.

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- 3. Pfizer portal at Theranos. Please provide me access to the Pfizer portal at Theranos. Login information is in Stefan's 11/18 email entitled "Theranos web portal access." I have downloaded the data has been downloaded as an Excel file. The data was not consistently collected on each patient. Only about 10% of the anticipated 250 patient study were enrolled and collected.
- 4. What are the assays that are currently run? Is the list on Slide 8, Introduction to the Theranos System the current list? Any analyte to which there are commercially available reagents can currently be run in the system. Assays for proprietary reagents are also developed in collaboration with our clients.
- 5. How many assays are currently run in multiplex mode? Up to eight are run on a single cartridge, but multiple cartridges work in the same machine, so different panels are often rotated for use on different days when patients monitor at home.
- 6. What are the multiplex assay panels? For this study, VEGF and PIGF were requested. We added VEGFR2 to that combination.
- 7. The VEGF, sVEGFR2 and PIGF were done as a multiplex assay? What was the sample type? Blood, serum or urine? Multiplexed, in whole blood, plasma and serum.
- 8. What were the calibrators? Calibrators are authentic materials spiked in proprietary matrix and adjusted for sample matrix effects.
- 9. Were they done in the same sample type? Yes.
- 10. What was the reference method used? References used were R&D kits for individual VEGF, VEGFR2, PLGF.
- 11. Was the reference assay a multiplex assay or three single assays? To our knowledge, there are no multiplexes other than Theranos' that function as well as individual kits do.
- 12. Where was it run? All reference methods are run at a Theranos facility.
- 13. Who ran it? Theranos employees in Quality Control.
- 14. How often does the instrument need to be calibrated? The instrument is calibrated at Theranos prior to shipment and then requires no further calibration in the field.
- 15. How often do the on board chemistry controls need to be run? They are customizable but are often run in each cartridge.
- 16. What is the process from finger prick to blood sample to the assay cartridge? Is

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this integrated or does the patient prick the finger then squeeze blood into an orifice of the assay cartridge? Does the instrument receive a finger into an orifice, prick and process into plasma? Patients who need to can use a transfer pen, and clinicians can use a pipette to run venous draws/plasma. Please see attached document entitled "ClinicianGuideB&W\_US\_small," which outlines that procedure.

- 17. Why is the Theranos VEGF and VEGFR2 assay not interfered with by Avastin but the reference method assay(s?) for VEGF and VEGFR2 are interfered? Theranos reagents are superior to R&D kits.
- 18. Was there longitudinal time correlation of changes in VEGF, PlGF and VEEGFR2 with CT-MRI tumor reduction? Was any other tumor load reduction measured and correlated with these three analytes? For the patients for whom we were able to get that data, yes. Please refer to final study report, emailed on 11 Nov.
- 19. Slide 12, Introduction to the Theranos System shows a C peptide measurement and correlated to a reference assay. What was the reference assay, where was it run and by who? How many patients are there in this slide? These were from studies run by other pharmaceutical clients. Please see attached document entitled "Theranos Evaluation Summary GSK Biomarker Lab."
- 20. Slide 17, Introduction to the Theranos System shows a patient with a 30 day longitudinal time measurement. How many patients were so measured out of the number enrolled? Please provide this type of plot for all of the patients measured. Was there any correlation of responders versus non-responders? Or level of response? Shown on TheranOS web portal and data from final report.
- 21. Slide 21, Introduction to the Theranos System show three patients with 72 hour longitudinal time measurements. How many patients were so measured out of the number enrolled? Please provide this type of plot for all of the patients measured. Was there any correlation of responders versus non-responders? Or level of response? These are also studies run by other pharmaceutical clients. Please see attached document entitled "Novartis\_Inflammation\_Report-c."
- 22. Do you have data and reports that address these goals from the September 2006 Study Plan? If so please send. Is the Introduction to the Theranos Systems slide deck the report that addresses these goals below? Yes. The web portal and the study report address the goals.
- 23. Is there an instrument version that measures single nucleotide polymorphisms? Requires customization.
- 24. Is there an instrument version that detects antibiotic resistant organisms? Requires customization.

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- 25. Can the instrument take a swab sample? The system can process saliva.
- 26. Is there a site in the Mid-Atlantic or New England that I could visit to see the instrument? We have teams in New Jersey who can bring a unit to your site. I have also attached an overview of the technology, per your request on our phone call.

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Theranos Background Web Documents of Interest: <a href="http://venturebeat.com/2006/12/07/theranos-raises-285m-for-device-tracking-effects-of-device-trackin drugs-on-patients/

http://www.jobvent.com/companyBrowse.php?CompanyID=5038

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